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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,276	01/02/2004	Sebastiano Scarampi	033292-004	7478
21839 7590 01/06/2009 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER GHALI, ISIS A D	
			ART UNIT 1611	PAPER NUMBER
			NOTIFICATION DATE 01/06/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/751,276	<b>Applicant(s)</b> SCARAMPI ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 6-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' request for RCE filed 10/09/2008.

Claims 1-36 are pending.

1. This application contains claims 6-16 drawn to nonelected invention with traverse and claims 17-36 drawn to nonelected inventions without traverse in the reply filed on 05/11/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-5 are included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/09/2008 has been entered.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,001,688 ('688) in view of US 7,074,392 (392).

CA '688 teaches topical composition for treating human nails comprising 6.25% Gilsonite, mineral oil carrier, preservative, and 3% of soybeans that reads on the bioactive agent (page 3, 1<sup>st</sup> paragraph; page 5, 3<sup>rd</sup> full paragraph; page 6, 1<sup>st</sup> paragraph; page 8, 2<sup>nd</sup> and 4<sup>th</sup> paragraphs). Gilsonite with mineral oil carrier expected to form gilsonite oil since gilsonite is soluble in hydrocarbon solvent (mineral oil) and because

Art Unit: 1611

compounds and their properties are inseparable. CA '688 further teaches the composition further comprising antibacterial and antifungal agents (page 3; page 5, last paragraph).

Although CA '688 suggested bioactive agents including antibacterial agent in the composition applied to the nails, however, does not explicitly teach hydrocortisone, nicotine, or caffeine as instantly claimed by claim 1.

US '392 teaches sustained release nail treating composition comprising antibacterial agents and antipsoriatic agent, with hydrocortisone is preferred antipsoriatic agent in an amount of 0.1-10% (abstract; col.3, lines 36-39; col.4, lines 46-50; col.14, lines 45-49). The composition is suitable to treat nail and surrounding tissues and it reduces the unwanted side effects caused by high concentration of the antimicrobial agents (col.3, lines 24-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails comprising Gilsonite and antimicrobial agent as disclosed by CA '688, and further add hydrocortisone to the antimicrobial agent or replace antimicrobial agent with hydrocortisone disclosed by US '392 according to the condition to be treated. One would have been motivated to do so because US '392 teaches that antimicrobial agents can be administered with hydrocortisone to the nails and further teaches that hydrocortisone is one of the preferred active agents to treat psoriasis of the nails and surrounding tissues and composition comprising hydrocortisone reduces the unwanted side effects caused by high concentration of the antimicrobial agents. One would reasonably

expected formulating topical composition for treating human nails comprising Gilsonite and antimicrobial agent and/or hydrocortisone that successfully treats the nail and surrounding tissues without any unwanted side effects.

### ***Response to Arguments***

6. Applicant's arguments filed 10/09/02008 have been fully considered but they are not persuasive. Applicants argue that reference teaches gilsonite that is different from the claimed gilsonite oil.

In response to this argument, it is argued that by Applicant's own admission, gilsonite is soluble in aliphatic, aromatic and chlorinated hydrocarbon solvents. CA 688 discloses gilsonite in mineral oil carrier. By the broadest reasonable interpretation, the gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitably lead to some if not all of the gilsonite solubilizing into mineral oil to form gilsonite oil. Further, gilsonite oil is a component of gilsonite, therefore when gilsonite is dissolve in the hydrocarbon solvent, the gilsonite oil will be present. In view of the claimed wide range of gilsonite oil starting from concentration as low as 0.0001%, any amount of gilsonite oil produced from solubilizing of gilsonite in the mineral oil of the reference will read on the claims.

Moreover, in view of applicants' disclosure in the specification of various grades and various colors and viscosities, the gilsonite mixed with mineral oil reads on the gilsonite oil. The instant specification fails to set forth any specific grade, colors, or viscosity of gilsonite oil suitable for the claimed composition. Rather it provides panoply

Art Unit: 1611

of generalized gilsonite oils which embrace the teachings of CA '688 patent. Therefore, absent a specific gilsonite oil which is suitable for the claimed composition, it is expected that any gilsonite oil falling within the general teachings of applicant's specification will yield the claimed composition.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

### ***Response to Amendment***

7. The declaration under 37 CFR 1.132 filed 08/27/2008 is insufficient to overcome the rejection of claims 1-5 based upon U.S.C. 103 (a) over the combination of CA '688 and US '392 as set forth in the last Office action because: it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The declaration states that Gilsonite oil was not available from American Gilsonite Corporation until at least as early as January 2000, however, the disclosure of Forrest (US Patent No. 1,573,765) provides evidence "gilsonite oil" and the fractionation of the oil was known way before the time of the CA '688 application. With regards to gilsonite with mineral oil, as disclosed above the gilsonite in the presence of a hydrocarbon solvent (mineral oil) would inevitable lead to some if not all the gilsonite solubilizing into solution, thereby the oil of the gilsonite would be extracted into the composition in the form gilsonite oil. In view of applicants' disclosure in the specification of various grades and with various viscosities, the gilsonite mixed with mineral oil reads on the gilsonite oil. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.



8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

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